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Ref: 8EPR-SR November 6, 2006

Ms. Gayla Benefield, Chair
Libby Area Technical Assistance Group, Inc.
P.O. Box 53
Libby, MT 59923

Re: Sampling and Analysis Plan for
Outdoor Ambient Air Monitoring at the
Libby Asbestos Site
dated September 28, 2006

Dear Ms. Benefield:

On behalf of the Environmental Protection Agency, Region 8 (EPA), I am pleased to transmit the enclosed document, "Final Sampling and Analysis Plan for Outdoor Ambient Air Monitoring at the Libby Asbestos Site, Libby, Montana" (Ambient Air SAP). As you may recall, the document was developed by EPA to guide the collection of data on levels of Libby amphibole in outdoor ambient air within the commercial and residential areas of Libby. A draft version of the Ambient Air SAP was provided to the Libby Area Technical Assistance Group (LATAG) and other interested parties in September, 2006 for review. Thank you for providing comments on the draft version on behalf of the LATAG. The enclosed final version of the Ambient Air SAP reflects modifications that EPA made to address comments we received from the LATAG and other reviewers. I've also enclosed responses to the comments EPA received from you on behalf of the LATAG in your letter of September 15, 2006.

We expect that future modifications will be need to be made to the Ambient Air SAP as it is implemented in the field and we learn more about how to best collect and analyze ambient air samples. EPA will transmit ~~modifications~~ revised SAP documents to you as they are made.

Thank you for your comments on the Ambient Air SAP as well as your input into the development of the program. If you have any questions about it, please don't hesitate to call me at (303) 312-6808.

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Sincerely,

Paul Peronard
EPA Team Leader
Libby Asbestos Site

Enclosures
cc (w/enclosures): Dr. Gerry Henningsen

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EPA Responses to LATAG's Major General Comments on the Draft Sampling and Analysis Plan for Outdoor Ambient Air Monitoring at the Libby Asbestos Site, Operable Unit 4

LATAG Comment 1:

Soundness of conceptual approaches appears weak and uncertain, which may reduce the quality and usability of the data and results

a. Uncertainty exists in the risk-based concentration (RBC) due to a lack of CSF and RfC benchmarks for LA (Libby Amphibole) asbestos; the SAP uses chrysotile-driven values from EPA's IRIS (integrated risk information system) database of 0.23 "unit cancer risk" per fiber/ml, based upon PCM "structures" that are >0.4 um diameter and >5um long, and this translates to $1x10^{-4}$ cancer risk at 0.0004 f/ml or $1x10^{-5}$ cancer risk at the SAP's target analytical detection limit of 0.00004 f/ml adjusted as PCM structures with diameters >0.4 um and lengths >5um (uncertain quantitation limit) – but all this is still based on CHYSOTILE, and the identical approach would most likely be used by EPA if they were assessing exposures and risks for a site that only has chrysotile contamination, thus this approach is weak and flawed from the start.

b. Reasonable estimates of LA asbestos potency range from about 10 to about 1000 fold more potent than chrysotile, probably due to tremolite asbestos content; while the EPA unit risk value has some contribution from amphiboles, it appears to be driven by mostly chrysotile studies and results, and therefore likely underestimates LA risks; if it turns out later that these estimates of greater potency are accurate, then the RBC and analytical methods must be correspondingly reduced by the difference in potency

c. Use of $1x10^{-5}$ for the cancer risk endpoint in the draft SAP, instead of the usual unit risk endpoint at $1x10^{-4}$ provides some extra relative reduction in uncertainty of estimated RBC endpoint for LA, but the lowered analytical concentrations needed to quantitatively evaluate results in respect to undefined RBCs are therefore uncertain in their ability to quantitate the results or to confidently interpret the non-detect values.

EPA Response:

EPA acknowledges the potential limitations associated with the use of the Integrated Risk Information System (IRIS) unit risk value for estimating risks from exposures to LA. It is the Agency's intention to account for ~~this~~ uncertainty in the Baseline Risk Assessment and in subsequent risk management decisions. However, EPA believes that the relative magnitude of the differences in potency is less than that suggested by the reviewer for several reasons.

First, the potency factors that are the basis for the current IRIS unit risk factor are derived from a multiple ~~mixture of~~ studies, including several that consider exposure to mixed or primarily amphibole asbestos (USEPA,1986).

Disease	Total Studies	Primarily Chrysotile	Mixed	Primarily Amphibole
Lung Cancer	11	6	4	1
Mesothelioma	4	1	2	1

Second, although scientific consensus has not yet been reached, EPA understands and agrees that the weight of evidence indicates that amphiboles are more potent than chrysotile for lung cancer and especially for mesothelioma. For example, the evaluations described in USEPA 2003 suggest the potency factor for lung cancer is about 5-fold higher for amphibole than chrysotile, and about 750 times higher for mesothelioma. However, this doesn't mean that risks for LA computed using the USEPA 1986 model will be between 5-750 times too low since 1) the IRIS unit risk is not based on chrysotile alone, but is also influenced by amphibole (see table above), and 2) the different risk models require different structure concentration units for inputs. For example, for the USEPA 1986 model, concentration must be expressed in units of PCM structures per cubic centimeter (cc). For the USEPA 2003 risk model, concentrations must be expressed in terms of "protocol structures" (thinner than 0.4 um, longer than 10 um) per cc. As an illustration, assume that the ratio of potency factors is 100 to 1, and the ratio of concentration values is 1 to 100. Then, the two models would yield equal risk results. At the Libby Site, when the USEPA 2003 risk model is used to evaluate risks from LA, the resulting risk estimates for lung cancer plus mesothelioma (combined) are less than 3-fold higher than predicted by the USEPA 1986 risk model.

Third, EPA intends to estimate the concentration of PCM structures or protocol structures by counting "total LA structures" and then multiplying by the fraction of total structures that are PCME or protocol. This approach was discussed in the Technical Memorandum "Libby Asbestos Site Residential/Commercial Cleanup Action Level and Clearance Criteria" (USEPA, 2003b). This approach is advantageous because quantification of relatively infrequent structures can be derived with high confidence at a much reduced analytical cost. That is, suppose the target sensitivity based on the USEPA 1986 risk model were 0.00004 s/cc. If total TEM structures are then counted, and if PCME are 50% of the total, the equivalent sensitivity is equal to 0.00004 / 2 = 0.00002 s/cc.

LATAG Comment 2:

objectives and goals are vague or weakly stated

a. the premise of this SAP for its scientific logic is unconvincing, while political or other non-technical objectives and goals may be the primary impetus for this SAP
b. pre-mature, rejected earlier ambient air report, R8 scientists said it was so bad that it would be buried and forgotten, but Max D proudly hailed in his June memo to LATAG

EPA Response:

The Final Sampling and Analysis Plan for Outdoor Ambient Air Monitoring at the Libby Asbestos Site, Operable Unit 4 (Ambient Air SAP) was developed by EPA to address the problem described in section 3.1 of the document. That is, one exposure pathway at the Libby Site that is of potential concern to EPA is inhalation of LA in outdoor ambient air within the town of Libby. However, the current data set for LA concentrations in outdoor ambient air in Libby is not extensive enough to support risk assessment calculations for this exposure pathway with acceptable levels of confidence because the data may not be fully representative over geographic area and/or time, and because many of the data have a high (poor) analytical sensitivity, which tends to limit confidence in estimates of long-term average exposure levels. EPA developed the Ambient Air SAP to guide the collection of reliable and representative (over space and time) data on the long-term average concentration of LA in outdoor air within an exposure unit at the Site. These data may then be analyzed using appropriate statistical methods to determine if there are important spatial patterns or important time trends in the data. EPA assures the LATAG that the main objective of the Ambient Air SAP is to support technical evaluations. EPA followed the seven-step Data Quality Objectives Process to ensure the type, quantity, and quality of environmental data collected under the Ambient Air SAP is sufficient to support the decisions that are intended to be made with the data.

LATAG Comment 2 (continued):

c. general common-sense questions like, "what is your RBC (Risk-Based Concentration as # fibers / cm3) that you are using for this SAP?" cannot be accurately defined

   - What science is your RBC based upon? Is it any good or is it a wild guess?
   - How certain or uncertain is the science behind RBCs? i.e., what are the ranges of possible errors in risk?
   - Shouldn't you first know your toxicology to derive a solid RBC?
   - What is the upper end of the RANGE of RISK estimated by ND (non-detect) concentrations? Our TA had estimated an extra 1 in 100 cancer risk at the old ~DL (Detection Limit) or about 1 in 1000 upper bound for the new DL of 0.00004?!?
   - If LA asbestos is much more potent than chrysotile, for which these analytical methods were developed, then why not wait and at least TRY to have your EPA or contract lab chemists lower the DLs???
   - What would it hurt EPA to re-prioritize their efforts towards getting the more critically needed "relative toxicity" screening study done in 6-9 months (estimated by some experts) and simultaneously task your chemists to explore options to lower and automate methods?
   - Why can't counting of fibers be automated as are many similar particulates, using instrumented microscopes and software that is faster, accurate and cheaper overall?

- Given the flawed earlier ambient air study and report with essentially the SAME methods to collect fibers and to count them, isn't EPA taking excessive risks of possible failure by

repeating the same findings – except for samples being taken from more wide-spread areas and over more seasons, and "planning to get ~ 10x lower detection limits?

- If so, why not wait and improve EPA's chances to SUCCEED, by doing a quick tox screening study to better understand relative potency of LA, which directly corresponds to how much lower the analytical methods must push down the DLs to help interpret data in terms of EPA's risk-based health criteria? Please explain your pros and cons for pushing ahead now prematurely with the same inadequate tools and knowledge, vs getting those essential tox data and refining methods as needed for the relative toxicity; then EPA could confidently proceed with reasonable assurance of success, since you would know your toxic target and could have improved methods, which would allow you to better interpret the data and put them into realistic science perspectives.
- If you are in fact, more or less proceeding with the same substandard methods and large uncertainties that plagued the earlier ambient air study and report, then we strongly suggest that EPA halt this effort immediately and wait until the higher priority tox studies and refinement of analyses are ready to use in such an air study; else it appears that EPA will waste more time and money by disappointing more residents with possibly very weak or relatively uninformative data.

EPA Response:

Section 3.7.2 of the Ambient Air SAP describes the basis for the required analytical sensitivity and presents the equation for estimating human health risk associated with a specified concentration of LA in air. The sensitivity specified in the Ambient Air SAP represents the best that can realistically be achieved at the current time using currently available analytical techniques. Section 5.1 of the Ambient Air SAP specifies that all samples not planned for immediate analysis will be archived and that all samples, once analyzed, will be archived at the on-site laboratory under chain-of-custody until further notice. If a future change in the risk assessment methodology does result in the need to improve sensitivity in the analysis of the samples and analytical methodology allows, the filters can be retrieved from archive and can be analyzed to a higher number of grid openings, achieving the target sensitivity that may be needed.

While EPA acknowledges that some uncertainties in the toxicology of asbestos remain and we understand and respect the LATAG's suggestion that EPA wait to implement an outdoor ambient air monitoring program until toxicological studies are performed and analytical techniques are refined, EPA's view is that the uncertainty is not a sufficient reason to delay collection and analysis of outdoor ambient air samples in accord with the Ambient Air SAP. EPA believes timely implementation of the Ambient Air SAP is the responsible course of action from a public health standpoint.

References:

USEPA 1986. Airborne Asbestos Health Assessment Update. Report 600/8-84-003F. U.S. Environmental Protection Agency, Office of Health and Environmental Assessment.

USEPA 2003a. Technical Support Document for a Protocol to Assess Asbestos-Related Risk. Report 9345.4-06, prepared for U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response by Berman DW (Aeolus Inc) and Crump K (Environ Corp).

USEPA 2003b. Libby Asbestos Site Residential/Commercial Cleanup Action Level and Clearance Criteria. USEPA Region 8 with technical assistance from Syracuse Research Corporation. December 15.

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REMARKS

Hi ALL!

ENCLOSED, FINALLY, IS A TRANSMITTAL LETTER FOR THE FINAL AMBIENT AIR SAP AND RESPONSES TO LATAG COMMENTS. PLEASE MARK UP ANY CHANGES AND/OR INITIAL YOUR CONCURRENCE. THANKS!

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

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